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SCIENTIFIC SUB-COMMITTEE

NS0044E1 (+ Annex)

17th Session

O. Eng.

Brussels, 30 November 2001.

PROPOSAL BY THE US ADMINISTRATION TO AMEND THE NOMENCLATURE AND EXPLANATORY NOTE TO HEADING 38.21

(Item II.7 on Agenda)

Reference documents:

NR0154E1 (RSC/23) NR0165E2, Annex D/3 (RSC/23 - Report) NC0368E1 (HSC/27) NC0430E2, Annex F (HSC/27 - Report)

I. BACKGROUND

- The Review Sub-Committee, at its 23rd Session, examined a proposal by the US Administration to amend the Nomenclature and Explanatory Note to heading 38.21 (see Doc. NR0154E1).
- 2. The Delegate of Canada explained that although culture media for the development of micro-organisms are used in a manner similar to those for higher organisms (eukaryotic cells), and may contain some of the same ingredients, there are differences due to the nutritional and environmental requirements of the two types of cells. Although the US proposal would therefore broaden the scope of heading 38.21, Canada felt that the proposal was logical and supported it in principle.
- 3. However, he felt that further review would be required. In Canada's view, the proposed amendments to the Explanatory Note to heading 38.21 should include a reference to media for the development of plant cells. Furthermore, as prokaryotes and eukaryotes together encompassed all living cells, the heading text could be modified to read "Prepared culture media for the development of living cells".

File No. 2844

- 4. He also pointed out that present heading 38.21 included media for the development of viruses. However, since viruses were not cellular, the proposed text would not be appropriate. Furthermore, the use of the word "development" in the proposed heading text would be restrictive and would not cover culture media used to preserve living cells for later study. The inclusion of the word "maintenance" in the proposed Explanatory Note recognised that such media should also be covered.
- 5. Accordingly, the Delegate of Canada suggested the amendment of the heading text to read simply "Prepared culture media" in order to cover all culture media used for the development and preservation of all living cells and viruses.
- 6. Another delegate suggested that, in view of the technical nature of the proposal, it would be appropriate to refer this issue to the Scientific Sub-Committee to clarify whether the scope of the heading would be widened and the nature of the transfers, if any. He also suggested that the Scientific Sub-Committee should provide its views on the text of the proposed Explanatory Note and the definitions of eukaryotic and prokaryotic cells.
- 7. The Sub-Committee agreed to this suggestion and decided to refer the US proposal and the above-mentioned Canadian comments to the Scientific Sub-Committee for advice on the points raised in paragraph 6 above (see Annex D/3 to Doc. NR0165E2).

II. SECRETARIAT COMMENTS

Amendments to the Nomenclature

8. Present heading 38.21 reads "Prepared culture media for development of microorganisms". The proposal by the US Administration to amend the text of this heading reads as follows:

"Prepared culture media for the development of prokaryotic and eukaryotic cells."

- 9. All cells are classified into two groups, prokaryotic and eukaryotic cells (McGraw-Hill ENCYCLOPEDIA of SCIENCE and TECHNOLOGY, volume 3, page 366). The definitions of prokaryotic and eukaryotic cells have been set out in the footnotes of the Annex to Doc. NR0154E1 as follows:
 - " Prokaryotic cells, or prokaryotae, are defined by <u>Dorland's Illustrated Medical Dictionary</u> (27th Edition) as "consisting of cellular organisms that lack a true nucleus (the bacteria).

 Eukaryotic cells, or eukaryotes, are defined by <u>Dorland's</u> as organisms "whose cells have a true nucleus, i.e., one bounded by a nuclear membrane, within which lie the chromosomes combined with proteins, and that exhibit mitosis; eukaryotic cells also contain many membrane-bound compartments (organelles) in which cellular functions are performed. The cells of higher plants and animals, fungi, protozoa and most algae are eukaryotic."
- 10. As pointed out by the Canadian Administration in paragraph 2 above, the US proposal would broaden the scope of heading 38.21 in that culture media for the development of eukaryotic cells (higher organisms) would be transferred from (perhaps) heading 38.24 to heading 38.21. However, the proposed text would reflect the state of current technological development and the Secretariat supports the proposal.

11. As pointed out in paragraph 4 above, the US proposal would exclude culture media for the development of viruses. In this respect, it should be noted that the current wording of heading 38.21 would cover such media as confirmed by the Explanatory Note to that heading. Therefore, the scope of the proposed text would become narrower than the present one in this regard. The Secretariat therefore shares the view of Canada and takes the view that the US proposal with regard to heading 38.21 should read simply "Prepared culture media".

Amendments to the Explanatory Notes

- 12. Since the proposed amendment of the Explanatory Note to heading 38.21 covers media for eucaryotic cells, the Secretariat agrees with this proposal, subject to the inclusion of the reference to "plant cells" as mentioned in paragraph 3 above.
- 13. Furthermore, it should be noted that the first sentence of the proposed new fifth paragraph may mislead readers to understand that only mammalian, avian, insect, fish and plant cells are eucaryotic cells. However, it should be noted that even present heading 38.21 covers culture media for certain eucaryotic cells such as mould, as mentioned in the present first paragraph of the Explanatory Note to heading 38.21. Therefore, the Secretariat would propose that the first sentence of the new fifth paragraph be redrafted as follows:

"This heading also covers prepared culture media intended for the growth, development and maintenance of eucaryotic cells of higher organisms such as mammalian (including human), avian, insect, fish and plant cells."

- 14. As for culture media for the development of viruses, since the present Explanatory Note covers such media, it would not be necessary to amend the Explanatory Notes in this regard.
- 15. The Secretariat has reproduced the US proposal with regard to the Nomenclature and the Explanatory Note to heading 38.21 subject to the above-mentioned modifications in the Annex to this document.

III. CONCLUSION

- 16. The Sub-Committee is invited to examine :
 - 16.1. whether the US proposal to amend heading 38.21, as modified by Canada would widen the scope of heading 38.21 and if so, what types of transfers would take place;
 - 16.2. whether the texts of the Explanatory Note as set out in the Annex hereto are well drafted to reflect the scope of new heading 38.21;
 - 16.3. whether the definitions of procaryotic and eucaryotic cells provided in paragraph 9 above are well founded.

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Annexe au Annex to Doc. NS0044B1 (SCS/17/janv. 02) (SSC/17/Jan. 02)

ANNEXE

AMENDEMENTS DE LA NOMENCLATURE ET DE LA NOTE EXPLICATIVE EN CE QUI CONCERNE LE N° 38.21

(Point II.7 de l'ordre du jour)

ANNEX

AMENDMENTS TO THE NOMENCLATURE AND EXPLANATORY NOTE TO HEADING 38.21

(Item II.7 on Agenda)

PROCEDURE DE L'ARTICLE 16

A. AMENDMENTS DE LA NOMENCLATURE

N° 38.21. Libellé de la position.

Nouvelle rédaction :

"Milieux de culture préparés."

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B. MODIFICATIONS DES NOTES EXPLICATIVES

N° 38.21.

1. Page 577 [694]. Nouveau cinquième paragraphe.

Insérer le nouveau cinquième paragraphe ci-après :

"La présente position comprend également les milieux de culture préparés destinés à la culture, au développement et à l'entretien <u>des cellules eucaryotes (cellules de mammifères (y compris les cellules humaines), d'oiseaux, d'insectes et de poissons, par exemple) (needs to be translated).</u>

Ces milieux contiennent souvent des sels organiques, des acides aminés, des vitamines, des hydrates de carbone et autres métabolites et constituants cellulaires nécessaires à la culture de la cellule et à sa fonction biologique."

2. Page 578 [694]. Premier paragraphe [Paragraphe cinq actuel].

Insérer la nouvelle dernière phrase ci-après :

"Elles peuvent également se présenter dans des conteneurs en vrac, en matière plastique ou en acier inoxydable."

Annex to Doc. NS0044B1 (SSC/17/Jan. 02)

ARTICLE 16 PROCEDURE

A. <u>AMENDMENTS TO THE NOMENCLATURE</u>

Heading 38.21. Heading text.

Delete and substitute:

"Prepared culture media."

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B. AMENDMENTS TO THE EXPLANATORY NOTES

Heading 38.21.

1. Page 577 [694]. New fifth paragraph.

Insert the following new fifth paragraph:

"This heading also covers prepared culture media intended for the growth, development and maintenance of eukaryotic cells of higher organisms such as mammalian (including human), avian, insect, fish and plant cells. Such media often contain organic salts, amino acids, vitamins, carbohydrates and other metabolites and macromolecular constituents required for cell growth and biological function."

2. Page 578 [694]. First [Present fifth] paragraph.

Insert the following new last sentence:

"They may also be put up in bulk containers, of plastics or of stainless steel."

(Note): The references in square brackets relate to the HS 2002 version of the Explanatory Notes.
